

## REMARKS

The office action dated March 9, 2006 (the "Office Action") has been received and carefully noted. Claims 1-96 were examined. Claims 13-16, 29-32, 47-50, 59-62, 88 and 91 are withdrawn from consideration. Claims 1-12, 17, 18, 34-46, 51-58, 63-87, 89, 90 and 92-96 are rejected. Claims 1-2, 5, 17, 33, 51, 56-57, 72-73, 78, 81-83, 85, 87, 89, 92 and 95 are amended. Support for the amendments can be found in, for example, ¶¶ [0092], [0058], [0077], [0082] and [0085]. As such, no new matter has been added. Claims 4, 20, 54-55, 86 and 96 are cancelled. Claims 1-3, 5-12, 17-19, 21-28, 33-46, 51-53, 56-58, 63-85, 87, 89-90 and 92-95 remain in the Application.

The Abstract was objected to because it exceeded a 150 word maximum. Appropriate correction has been made pursuant to 37 C.F.R. §§ 1.72 and 1.121.

The Title was objected to because, according to the Examiner, it was not descriptive. Appropriate correction has been made pursuant to 37 C.F.R. § 1.121.

### **I. Claims Rejected Under 35 U.S.C. § 102(e)**

Claims 1-3, 7-8, 11-12, 17-19, 24, 27-28, 33-38, 42-43, 45-46, 51-55, 57-58, 63, 65, 67-81, 85-87, 89-90 and 92-96 were rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,692,466 to Chow et al. ("*Chow*"). A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP § 2131. Applicants respectfully submit that each and every element in independent claims 1, 17, 33, 51, 63, 72, 78, 85 and 92 and their respective dependent claims is not disclosed in the cited references.

Independent claims 1 and 17, as amended, include the limitations of "a needle . . . having *a protuberance . . . a first stop* disposed in the lumen of [an] at least one delivery cannula at a position distal to the protuberance on the needle . . . [and] *a second stop* disposed in the lumen of the at least one delivery cannula at a position proximal to the protuberance on the needle." (Claims 1, 17) *Chow* describes a needle with a mechanical stop 80 including a ring stop 82 attached to delivery lumen 40 and a contact stop 84 coupled to needle 46 (cols. 5-6, lns. 62-67, 1-16) Thus, *Chow* does not disclose the elements of a protuberance on the needle, a first stop

within the lumen and a second stop within the lumen. Accordingly, Applicants respectfully submit that independent claims 1 and 17 and their respective dependent claims are patentably allowable over *Chow*.

Independent claim 33 includes the limitation of “a sheath ring circumferentially ***disposed about the at least one delivery cannula*** proximately adjacent the plication region.” (Claim 33) *Chow* discloses that the “mechanical stop 80 can be used to limit the travel of needle 46 ***within*** delivery lumen 40.” (col. 5, lns. 63-64) Thus, *Chow* does not disclose the limitation of a sheath ring circumferentially disposed about the at least one delivery cannula. Accordingly, Applicants respectfully submit that independent claim 33 and its respective dependent claims are patentably allowable over *Chow*.

Independent claim 51 includes the limitation of “***a protuberance*** coupled to the needle at a portion within the hub.” (Claim 51) *Chow* describes a hub 51 that provides “access to the proximal end of delivery lumen 40 for insertion of needle 46.” (col. 5, lns. 3-5) Applicants are unable to discern in any part of *Chow* a protuberance coupled to the needle at a portion within the hub. Thus, *Chow* does not disclose all of the limitations of independent claim 51, namely, the limitation of a protuberance coupled to the needle at a portion within the hub. Accordingly, Applicants respectfully submit that independent claim 51 and its respective dependent claims are patentably allowable over *Chow*.

Independent claim 63 includes the limitation of “wherein the first cannula body and the second cannula body define a continuous lumen therethrough.” (Claim 63) Thus, the apparatus claimed by Applicants includes two separate cannula bodies forming one cannula body defining one continuous lumen. *Chow* describes a needle 46. (col. 5, lns. 32-61) Applicants are unable to discern in any part of *Chow* a first cannula body and the second cannula body defining a continuous lumen therethrough. Thus, *Chow* does not disclose all of the limitations of independent claim 63, namely, a first cannula body and the second cannula body defining a continuous lumen therethrough. Accordingly, Applicants respectfully submit that independent claim 63 and its respective dependent claims are patentably allowable over *Chow*.

Independent claim 72 includes the limitation of “a protuberance coupled to the needle, the at least one needle associated with the hub.” (Claim 72) *Chow* describes a hub 51 that provides

“access to the proximal end of delivery lumen 40 for insertion of needle 46.” (col. 5, Ins. 3-5) Applicants are unable to discern in any part of *Chow* a protuberance coupled to the needle, the at least one needle associated with the hub. Thus, *Chow* does not disclose all of the limitations of independent claim 72, namely, a protuberance coupled to the needle, the at least one needle associated with the hub. Accordingly, Applicants respectfully submit that independent claim 72 and its respective dependent claims are patentably allowable over *Chow*.

Independent claim 78 includes the limitation of “a hub coupled to a proximal portion of the cannula and retaining the at least one needle according to a prescribed radial orientation by a ***second protuberance on a proximal portion of the needle.***” (Claim 78) *Chow* describes a hub 51 that provides “access to the proximal end of delivery lumen 40 for insertion of needle 46.” (col. 5, Ins. 3-5) Applicants are unable to discern in any part of *Chow* a second protuberance on a proximal portion of the needle retained in a hub. Thus, *Chow* does not disclose all of the limitations of independent claim 78, namely, a second protuberance on a proximal portion of the needle. Accordingly, Applicants respectfully submit that independent claim 78 and its respective dependent claims are patentably allowable over *Chow*.

Independent claim 85 includes the limitation of “a needle comprising a proximal portion and a distal portion . . . wherein the distal portion has an inside diameter less than an inside diameter of the proximal portion.” (Claim 85) *Chow* describes a needle 46. (col. 5, Ins. 32-61) Applicants are unable to discern in any part of *Chow* a needle comprising a proximal portion and a distal portion wherein the distal portion has an inside diameter less than an inside diameter of the proximal portion. Thus, *Chow* does not disclose all of the limitations of independent claim 85, namely, a needle with varying diameter. Accordingly, Applicants respectfully submit that independent claim 85 and its respective dependent claims are patentably allowable over *Chow*.

Independent claim 92 includes the limitations of “maintaining a prescribed orientation of the at least one needle delivery device at a proximal end” and “maintaining a prescribed orientation of the at least one needle delivery device at a distal end.” (Claim 92) Applicants are unable to discern in any part of *Chow* limitations directed to maintaining prescribed orientations of a needle delivery device. Accordingly, Applicants respectfully submit that independent claim 92 and its respective dependent claims are patentably allowable over *Chow*.

## II. Claims Rejected Under 35 U.S.C. § 103

### A.

Claims 4-6, 9-10, 20-23 25-26, 44, 56, 82-83 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Chow* in view of U.S. Patent No. 6,835,193 to Epstein, et al. (“*Epstein*”). In order to establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the references when combined must teach or suggest all of the claim limitations. MPEP 2142. Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

More particularly, the references when combined do not teach or suggest all of the limitations of independent claims 1, 17, 33, 51, and 78. Independent claims 1 and 17 include the limitations of “a needle . . . having **a protuberance . . . a first stop** disposed in the lumen of [an] at least one delivery cannula at a position distal to the protuberance on the needle . . . [and] **a second stop** disposed in the lumen of the at least one delivery cannula at a position proximal to the protuberance on the needle.” (Claims 1, 17) As stated previously, *Chow* describes a needle with a mechanical stop 80 including a ring stop 82 attached to delivery lumen 40 and a contact stop 84 coupled to needle 46 (cols. 5-6, lns. 62-67, 1-16) *Epstein* describes an injection catheter with a needle 6 with “a needle stop mechanism<sup>14</sup> . . . compris[ing] one or more raised portions on the exterior of the needle and a retaining shoulder 20 in the interior of the catheter body.” (col. 6, lns. 44-47; FIG. 3) Thus, according to *Epstein*, although one or more raised portions can be on an exterior of the needle, the stop mechanism within the interior of the catheter body is limited to **a** retaining shoulder 20. Thus, *Chow* combined with *Epstein* does not teach or suggest the elements of a protuberance on the needle, a first stop within the lumen and a second stop within the lumen. Applicants are unable to discern in any part of *Epstein* a needle cannula system with multiple sleeves to stop the needle (both proximal and distal) and the partial sleeve changing the cross-section shape, or, a second protuberance that limits the total movement of the needle and provides an orientation within the lumen, as stated by the Examiner. Dependent claims 5-6, 9-10, 21-23 and 25-26 depend from independent claims 1 and 17 and therefore include all of their

limitations. Accordingly, Applicants respectfully submit that dependent claims 5-6, 9-10 21-23 are patentable over *Chow* in view of *Epstein*.

In addition, the references when combined do not teach or suggest all of the limitations of independent claim 33. Independent claim 33 includes the limitation of “a sheath ring circumferentially ***disposed about the at least one delivery cannula*** proximally adjacent the plication region.” (Claim 33) As stated previously, *Chow* discloses that the “mechanical stop 80 can be used to limit the travel of needle 46 ***within*** delivery lumen 40.” (col. 5, lns. 63-64) Thus, *Chow* does not disclose the limitation of a sheath ring disposed about the at least one delivery cannula. Applicants are unable to discern in any part of *Epstein* a sheath ring circumferentially disposed about the at least one delivery cannula proximally adjacent the plication region. Dependent claim 44 depends on independent claim 33 and therefore includes all of its limitations. Accordingly, Applicants respectfully submit that dependent claim 44 is patentable over *Chow* in view of *Epstein*.

In addition, independent claim 51 includes the limitation of “***a protuberance*** coupled to the needle at a portion within the hub.” (Claim 51) Independent claim 78 includes the limitation of “a hub coupled to a proximal portion of the cannula and retaining the at least one needle according to a prescribed radial orientation by a ***second protuberance on a proximal portion of the needle***.” (Claim 78) As stated previously, *Chow* describes a hub 51 that provides “access to the proximal end of delivery lumen 40 for insertion of needle 46.” (col. 5, lns. 3-5) *Epstein* describes a handle 28 (col. 10, ln. 7) Applicants are unable to discern in any part of *Chow* or *Epstein* a protuberance coupled to the needle at a portion within the hub. Dependent claims 56 and 82-83 depend on independent claims 51 and 78 and therefore include all of their limitations. Accordingly, Applicants respectfully submit that dependent claims 56 and 82-83 are patentable over *Chow* in view of *Epstein*.

B.

Claims 39-41 and 84 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Chow*. Applicants respectfully submit that a *prima facie* case of obviousness has not been established. More particularly, *Chow* does not teach or suggest all of the limitations of independent claims 33 and 78 as noted previously in detail. Dependent claims 39-41 and 84

depend on independent claims 33 and 78, respectively, and therefore include all of their limitations. Accordingly, Applicants respectfully submit that dependent claims 39-41 and 84 are patentable over *Chow*.

C.

Claims 64 and 66 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Chow* in view of U.S. Patent No. 6,302,870 to Jacobson et al. ("*Jacobson*"). Applicants respectfully submit that a *prima facie* case of obviousness has not been established. More particularly, *Chow* in view of *Jacobson* does not teach or suggest all of the limitations of independent claim 63. Independent claim 63 includes the limitation of "wherein the first cannula body and the second cannula body define a continuous lumen therethrough." (Claim 63) Thus, the apparatus claimed by Applicants includes two separate cannula bodies forming one cannula body defining one continuous lumen. *Chow* describes a needle 46. (col. 5, lns. 32-61) Applicants are unable to discern in any part of *Chow* a first cannula body and the second cannula body defining a continuous lumen therethrough. *Jacobson* describes an apparatus for injecting fluids into the walls of blood vessels including a plurality of laterally flexible needles disposed in a catheter for exit either out the distal end of the catheter or through corresponding side openings. (Abstract). Applicants are unable to discern in any part of *Jacobson* a first cannula body and the second cannula body defining a continuous lumen therethrough. Dependent claims 64 and 66 depend from independent claim 63 and include all of its limitations. Accordingly, Applicants respectfully submit that dependent claims 64 and 66 are patentable over *Chow* in view of *Jacobson*.

## CONCLUSION

In view of the foregoing, it is believed that all claims now pending, namely, claims 1-3, 5-12, 17-19, 21-28, 33-46, 51-53, 56-58, 63-85, 87, 89-90 and 92-95 patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 207-3800x766.

Respectfully submitted,

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